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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,049	07/30/2004	Bernd Stahl	STAH3008/REF	2144

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,049	STAHL ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-17 and 20-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-17 and 20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A Request for Continued Examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 10/14/08 has been entered.

The Request for Continued Examination filed 10/14/08 has been carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-13 and 18-19 have been canceled.

2. New Claims 29-31 have been added.

3. Claims 14-15, 17 and 24-27 have been amended.

4. Remarks drawn to rejections under obviousness-type double patenting, 35 USC 112, first and second paragraphs and 103(a) maintained in the previous action.

Claims 14-17 and 20-31 are pending in the case.

Claim Objections

Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 24 depends from claim 26 and not from a previous claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17, 20-23, 25 and 27-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the carbohydrate of formula I in combination with an auxiliary agent, diluent, moisturizing agent, thickening agent, flavoring agent, sweetening agent, carrier and food and a method of immunosuppression and treatment of infections, does not reasonably provide enablement for a method of preventing infections using the carbohydrate of formula I and a composition further comprising active agents(s) and ingredients. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims
(B) The state of the prior art
(C) The level of predictability in the art
(D) The amount of direction provided by the inventor
(E) The existence of working examples
(F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claims 14 and 21 are drawn to a method for prevention of infections. The scope of the claim is seen to include the administration of the said sialyzed carbohydrates to a healthy subject, wherein the said compound/composition prevents said disease from manifesting itself in the subject. Claim 25 recites the broad terms active agents(s) and ingredients. These broad terms are seen to include several compounds, both known and unknown at the time of filing.

The state of the prior art

The examiner notes that WO 00/46379 (cited by applicants) teaches sialyzed carbohydrates and compositions comprising them. However, there is no disclosure of potential prevention of any infection using the compounds/compositions seen in the prior art. The prior art appears to be silent with regard to preventive procedures recognized by skilled artisans in the field.

The level of predictability in the art

There is not seen sufficient data to substantiate the assertion that the infections may be prevented by the use of the composition and compounds as instantly claimed. According to The Merck Index (1992, pages 279-303) the immune system and its response is complicated and involves genetic factors too. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427.2d 833, 166 USPQ (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since on of skill in the art cannot fully visualize or recognize the identity

of the members of the genus. In the absence of fully recognizing the identity of the members of the genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having the claimed functional properties in the compositions herein. Goodman and Gilman's "The Pharmacological Basis of Therapeutics", 10th Ed., 1996, page 54, teaches that the frequency of significant beneficial or adverse drug interactions is unknown (bottom of the left column at page 54). Relatively small changes in the drug level can have significant adverse consequences. In the instant case one of skill in the art would not be able to fully predict possible adverse interactions occurring with the many combinations of any compounds having the functional properties in the pharmaceutical compositions claimed herein. Thus, the teachings of Gillman and Goodman clearly support that the instantly claimed invention is highly unpredictable.

The amount of direction provided by the inventor

The instant specification is not seen to provide sufficient guidance that would allow a skilled artisan to extrapolate from the disclosure and the limited examples provided to enable the use of the active agents, ingredients and compositions to enable the prevention as instantly claimed. The specification also fails to direct the skilled artisan to correlative prior art disclosures which teach procedures which might provide the basis for an advance in treating infections which encompasses prevention. The specification (page 9, line 14) mentions the terms, 'active agent(s)'. There is no definition provided for the said terms. There is no mention of the term 'ingredients'.

The existence of working examples

The working examples set forth in the instant specification are drawn to food and beverages comprising the carbohydrates of formula I. The skilled artisan in this field would not extrapolate the preventive efficacy of the compounds/composition claimed or the use of the same in preventive methods from the limited examples provided. There are no working examples that show the prevention of infection using the compounds/compositions of the instant invention.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the composition of claim 25 and prevention of infection with the compounds and compositions and method set forth in the claims. One of ordinary skill in the art would have to perform undue experimentation to find out which combinations of the sialyzed carbohydrates and the myriad of other active agents and ingredients give stable compositions and their preventive activities.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-17 and 20-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites structural formula (I) in which V is defined as an OH or carbohydrate residue or a carrier T and the carbohydrate or carrier is further defined as formula (II). This

means that that the carrier and carbohydrate residue are one and the same. The term carrier is also defined by the letter T, which means that it could be any moiety. It is not clear what applicants intend. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation carrier T, and the claim also recites carbohydrate residue, which is the narrower statement of the range/limitation. This lack of clarity is also seen in claim 26. Clarification is needed.

Claim 15, which depends from claim 14, recites that the carrier T is a peptide, a protein, a polymer of a biopolymer. But according to parent claim 14 the carrier is defined by formula (II). It is not clear what applicants intend. Also, according to the recitation of the parent claim 14, V can be a carbohydrate residue or a carrier T. But according to the recitation of dependent claim 15, the compound can have both the carbohydrate residue and the carrier T. This is not seen to further limit the parent claim. This recitation is also seen in claim 27 and in claim 27, wherein (in

claim 27) T is defined as lipophilic compounds. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 15 recites the broad recitation peptide, protein, and the claim also recites polymer, biopolymer, which is the narrower statement of the range/limitation. This recitation is also seen in claims 27 and 29.

Claim 15(i) recites N-glycolyl. Do applicants intend the glycol residue or do applicants intend N-glycosyl? This recitation is also seen in claim 27 (i).

Claim 20 recites, "at least 1mg of formula I per kg of body weight". It is not clear what applicants intend by the said recitations. The recitation, "at least" indicates that more than 1mg/Kg of body weight may be used. Since 1mg is the lower limit, the upper limit is not defined. This renders the claim indefinite.

Claim 22 recites the limitation "immunomodulation" in claim 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the terms, "further active agent(s), ingredients", without a definition. In the absence of the specific names or chemical structure, the identity of the said agents and ingredients, the metes and bounds of said agents and ingredients applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 25 recites the broad recitation ingredients, and the claim also recites diluent, moisturizing agents, etc., which are the narrower statement of the range/limitation.

Claim 26 recites, 'wherein formula I has at least one carbohydrate unit of formula II'. Formula I has the structure recited formula II in it. It is not clear what applicants intend.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 12-13 of copending Application No. 10/148,193('193). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claims 24 and 31 are drawn to a food, dietetic or pharmaceutical composition comprising the sialyzed carbohydrates of instant claims 26 and 29.

Claims 1, 3-7 and 12-13 of the copending '193 application are also drawn to the same type of compositions comprising of the same monomeric carbohydrate units.

Claims 1, 3-7 and 12-13 of '193 differ from the instant claims in that the instant claims can have a carrier. However, it would have been obvious to one of ordinary skill in the art at the

time the invention was made that the carbohydrates of the instant composition could be successfully employed in the composition of '193.

In determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). In the instant case, '193 teaches the use of each of the monosaccharide residues applicant claims. Although the claims of '193 also employ several other saccharide residues, one of ordinary skill in the art would readily recognize that the scheme taught by '193 could be employed in the instant composition too. The use of known members of classes of agents in compositions to make a similar type of composition taught in the prior art is not seen to render the instantly claimed composition unobvious over the art. Once the general scheme and the agents used has been shown to be old, the burden is on the applicant to present reason or authority for believing that the use of an additional carbohydrate residue or a carrier would affect or alter the nature of the product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 24 and 31 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Patent No. 6,576,251 ('251 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claims 24 and 31 are drawn to a food, dietetic or pharmaceutical composition comprising the sialyzed carbohydrates of instant claims 26 and 29.

Claims 1-10 of '251 are drawn to a food, dietetic or pharmaceutical composition comprising carbohydrate mixtures in a bound form, wherein the mono, oligo or polysaccharides are composed of units that are also seen in the instant claims.

Claims 1-10 of '251 differ from the instant claims in that the instant claims do not specifically recite the presence of fucose. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the carbohydrates of the instant composition could be successfully employed in the composition of '251.

In determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir.

2000). In the instant case, '251 teaches the use of each of the monosaccharide residues applicant claims. Although the claims of '251 also employ fucose, one of ordinary skill in the art would readily recognize that the scheme taught by '251 could be employed in the instant composition too. The use of known members of classes of agents in compositions to make a similar type of composition taught in the prior art is not seen to render the instantly claimed composition unobvious over the art. Once the general scheme and the agents used has been shown to be old, the burden is on the applicant to present reason or authority for believing that the use of an additional carbohydrate like fucose would affect or alter the nature of the product.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29 and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Gilbert et al (WO 00/46379; document cited in IDS of 30 July 2004).

Gilbert et al teach a carbohydrate comprising (labeled GT1a-, the second saccharide sequence from the bottom in Figure 4), which has all the components as recited in instant formula (I). It also has a neuraminic acid-5-acetate (acyl derivative) attached to the galactose (on the right). This is the same as the Hex attached to X in instant formula (I), wherein Hex is Galactose (Gal) and X is Neuraminic acid –5-acetate. The glucose moiety on the right side of the sequence is the carbohydrate residue or the carrier (T) as instantly claimed and n is 1 (limitations

of claim 29). Gilbert teaches pharmaceutical compositions of his compounds suitable for different modes of administration. The compositions include other agents/auxiliaries like buffers tonicity adjusting agents (page 41, line 20 through page 43, line 20; limitations of claim 31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-17 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al (WO 00/46379; document cited in IDS of 30 July 2004) of record.

Gilbert et al teach a carbohydrate comprising (labeled GT1a-, the second saccharide sequence from the bottom in Figure 4), which has all the components as recited in instant formula (I). It also has a neuraminic acid-5-acetate (acyl derivative) attached to the galactose (on the right). This is the same as the Hex attached to X in instant formula (I), wherein Hex is Galactose (Gal) and X is Neuraminic acid –5-acetate. The glucose moiety on the right side of the sequence is the carbohydrate residue or the carrier as instantly claimed and n is 1. Gilbert teaches pharmaceutical compositions of his compounds suitable for different modes of administration. The compositions include other agents/auxiliaries like buffers tonicity adjusting agents. The compositions can be administered for therapeutic treatment of a variety of conditions in doses ranging from 0.5mg to about 40g (page 41, line 20 through page 43, line 20) and suggests the administration of the oligosaccharides as immunogen (immunomodulation or suppression). However, Gilbert et al do not exemplify the method of immunomodulation or immunosuppression or treatment of infections specifically using the oligosaccharide described above, a food or dietetic composition comprising the oligosaccharides and the other derivatives as instantly claimed. But one of skill in the art reading the teachings of Gilbert will recognize that such oligosaccharides have the potential for use in methods of treatment as instantly claimed since their use in the treatment of a variety of conditions is suggested by Gilbert (page 41, lines 20-26). Since Gilbert also suggests oral administration, one of skill in the art will also recognize the use of these oligosaccharides in food compositions.

It would have been obvious to one of skill in the art at the time the invention was made to make the carbohydrates and derivatives of instant formula (I) and their compositions and use them in a method of treatment as instantly claimed since the use of carbohydrates that are structurally close to instant formula (I) is suggested in the prior art as a therapeutic agent for a variety of conditions.

One of skill in the art would be motivated to use the compounds as instantly claimed since they are close structural analogs and would look for such analogs with a high therapeutic index and would also expect them to work with a reasonable expectation of success.

Response to Applicants Arguments

In response to applicants' arguments the rejections above are made of record.

Regarding the enablement rejection under 35 USC 112, first paragraph maintained in the previous action applicants argue that the specification teaches how to practice the claimed invention, including how to prepare and deliver the recited sialyzed carbohydrates. The 35 USC 112, first paragraph above is made of record for lack of enablement for a method of preventing infections using the carbohydrate of formula I and a composition further comprising active agents(s) and ingredients. The teaching regarding how to practice the claimed invention, including how to prepare and deliver the recited sialyzed carbohydrates is not seen to be enabling for the said method of prevention and the compositions comprising any ingredient and active agents as broadly encompassed.

Regarding the obviousness-type double patenting rejection over claims 1, 6 and 9-10 of the '251 patent applicants have argued that claim 1 of the '251 patent recites that the composition

contains at least 1 wt% of fucose and in view of this the rejection should be withdrawn. This is not found to be persuasive. The '251 patent is drawn to a composition comprising monosaccharide units in as instantly claimed, including bound forms of the carbohydrate units. Since no specific bound form is recited in the '251 patent it is seen to include any sequence of bound forms including instant structure I. The instant claims also recite comprising including a carbohydrate residue for the unit V in instant formula I. This recitation is not seen to exclude fucose.

Regarding the 103(a0 rejection of record applicants have argued that Gilbert teaches that his gangliosides can be used as immunogens for the production of antibodies and as diagnostic agents. This does not render the instant invention obvious. This is not found to be persuasive. The use of gangliosides as immunogens for the production of antibodies and as diagnostic agents, as taught by Gilbert are two aspects of his invention. Applicants' methods of treatment as instantly claimed are also broad and can include a variety of conditions/infections and not limited to treating any specific condition or infection. Gilbert teaches that his compounds are useful for treating a variety of conditions. In addition to this he suggests the use of the compounds as immunogens. Even thought the use as immunogen is for making monoclonal or polyclonal antibodies, at page 43, lines 14-16, Gilbert discloses that animals can be immunized (immunomodulation or suppression) with a preparation containing the oligosaccharides of his invention. This is a suggestion regarding the method of use for the oligosaccharides as instantly claimed.

Conclusion

Claims 14-17 and 20-31 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623